EXHIBIT H

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
THIS DOCUMENT RELATES TO: *Mary Ward, et al. v. Ethicon, Inc.., et al No. 2:12-cv-02198*	**HON. JOSEPH R. GOODWIN**

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Motley Rice Law Firm to give medical opinions related to Mary Ward. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these

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devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including the pubovaginal sling. I have attended training provided by Ethicon, Inc. regarding the TVT device. I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Mary Ward:

- Catawba Valley Medical Center;
- Stephen McIntyre, MD;
- Viewmont Urology Clinic, P.A.;
- Catawba Women's Center, P.A.;
- Piedmont Pathology Associates ;
- Jerry L. Pruitt, M.D.;
- Catawba Radiological Associates, Inc.;
- Gastroenterology Associates, P.A.
- Hickory Cardiology Associates, PLLC;
- Neurology Associates of Hickory;
- Alicia M. Carroll, MD;
- OrthoCarolina;
- Conover Family Practice;

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- Deposition – Mary Ward; and
- Deposition – Jeffrey Ward

In addition to the review of the medical records listed above, I performed an independent medical examination of Mary Ward on June 17th, 2016. I have also reviewed medical literature and other TVM related documents and have relied, in part, on the documents enclosed in my reliance list provided as **Appendix A**.

Clinical History

- On February 14th, 2005, Mrs. Ward presented to Dr. Highland for her annual gynecological exam. She was placed on a Climara patch for cyclical headaches attributed to perimenopausal changes.

- On April 27th, 2005, Mrs. Ward saw Dr. DeLeary for evaluation of urinary incontinence. Medical records memorialize that the incontinence occurred with coughing, sneezing, laughing, moving and jumping. The patient also noted occasional urgency to void occurring at the time of her menses. Physical examination revealed urethral hypermobility. She was scheduled for cystoscopy and started on Enablex for intermittent bladder overactivity.

- On May 3rd, 2005, Mrs. Ward underwent cystoscopic evaluation by Dr. DeLeary. This revealed a normal urethra and bladder throughout. There were no lesions, ulcerations, or tumors seen. There was good efflux of clear urine bilaterally. The bladder was filled with approximately 400 cc and there were no uninhibited bladder contractions. Dr. DeLeary memorialized that she had failed medical management for her voiding dysfunction problems and recommended that she undergo a TVT sling procedure. Dr. DeLeary reviewed the risks and benefits of the procedure, memorializing "she does understand the risks and benefits of this including but not exclusive to

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infection, hematoma, bleeding pain and discomfort, urinary retention, urinary frequency, urgency and urinary incontinence.

- On June 20th, 2005, Mrs. Ward underwent implantation of a TVT sling by Dr. Geoffrey DeLeary. The procedure occurred uneventfully. An empty sponge stick was used as a spacer to ensure a tension-free setting. Estimated blood loss was 50 cc.

- On June 27th, 2005, Mrs. Ward saw Jerry Heath, P.A., under the supervision of Dr. Eller. She had gotten bored over the weekend and ended up traveling up to the mountains. She had a coughing spell there, and when she did, she felt some pain in the right side of the vagina and had noticed some blood since. On exam, there was some dark blood and clots in the vaginal vault. No active bleed was identified on exam at this time.

- On July 6th, 2005, she followed up with Mr. Heath under the supervision of Dr. DeLeary. Her vaginal bleeding had stopped as of June 27th, 2005 and she was voiding well, denying any leakage.

- On September 1st, 2005, Mrs. Ward saw Dr. Highland reporting regular menstrual cycles but continued headaches. She was started on Zomig for the treatment of her headaches.

- On April, 25th, 2006, because of dysfunctional uterine bleeding, Mrs. Ward underwent hysteroscopy and dilatation and curettage by Dr. Walker. He memorializes moderate uterine prolapsed and his curettings revealed endometritis and disordered proliferative endometrium. She was started on Loestrin 24.

- On July 14th, 2006, she underwent a sonohysterogram which revealed no abnormal findings.

- On March 16th, 2007, Mrs. Ward saw Dr. Highland with complaints of heavy vaginal bleeding despite Loestrin 24 medical therapy. At this

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time, Dr. Highland noted that she was interested in hysterectomy but wished to continue medical therapy.

- On October 31st, 2007, she was diagnosed with a UTI and prescribed Bactrim DS.
- On February 8th, 2008, she was diagnosed with bacterial vaginosis and prescribed Clindesse vaginal cream.
- On July 3rd, 2008, Mrs. Ward, saw Dr. Highland for her annual Gyn visit. Her vaginal bleeding was stable at that time.
- On September 28th, 2008, she presented to Conover Family Practice with complaints of vaginal burning, urinary frequency, body aches, low grade fever, low back pain, and pain in left side. She was diagnosed with a UTI and prescribed Bactrim DS.
- On April 17th, 2009, she was diagnosed with a Klebsiella UTI and prescribed Cipro.
- On April 29th, 2009, Dr. Highland performed an endometrial biopsy and saline infusion sonogram because of continued irregular bleeding. She was prescribed Aygestin and recommended to undergo endometrial ablation.
- On May 21st, 2009, she underwent NovaSure endometrial ablation which she tolerated well.
- On May 29th, 2009, she visited Conover Family Practice with a 4 day complaint of dysuria. She was diagnosed with a UTI and prescribed Cipro.
- On October 12th, 2009, she saw Dr. Highland satisfied with her endometrial ablation results. Dr. Highland reports that that she was not sexually active at that time and memorialized that her husband had been prescribed Viagra because of medication-related erectile dysfunction.

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- On March 24th, 2010, Mrs. Ward presented to Catawba Medical Center with complaints of a possible UTI. She had complaints of bladder spasms and urinary frequency. She had not been sexually active over approximately the last 4 years. She was empirically treated with Cipro and Pyridium.

- On April 16th, 2010, Mrs. Ward presented to Dr. Highland with complaints of recurrent UTIs and issues emptying her bladder. She was prescribed Cipro and Pyridium at that time

- On April 7th, 2013, Dr. Highland noted that Mrs. Ward's vaginal bleeding had worsened and that she was having some left-sided pain. She was advised to consider a laparoscopic-assisted vaginal hysterectomy and bilateral salpingo-oophorectomy (LAVH-BSO).

- On May 16th, 2014, Dr. Highland performed the LAVH-BSO procedure. The procedure occurred uneventfully with no unusual findings. She was prescribed oral Premarin thereafter.

- On June 6th, 2014, Dr. Highland prescribed Cipro for a UTI.

- On June 16th, 2014, Dr. Highland saw Mrs. Ward for a post-operative check. Her UTI symptoms had resolved and she was advised to resume normal activities at 6 weeks following this appointment.

- On March 23rd, 2015, Mrs. Ward presented to Dr. Highland with some vaginal bleeding. She reported no recent sex at that time. Two areas of tissue granulation were identified and treated with silver nitrate.

- On April 7th, 2015, she saw Dr. Highland again having had resolution of her vaginal bleeding. She was continued on Premarin therapy.

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Methodology

My general opinions are based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion that the IFU for the TVT in 2005 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.

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- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina and peri-vaginal tissues persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. These events were reported in the mid-urethral sling literature prior to when Mrs. Ward was implanted. In my opinion, a patient considering a mid-urethral

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sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2005 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.

In 2005, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Ward was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT IFU inherent to the risks of using synthetic mesh. As such, Dr. DeLeary was unable to warn Mrs. Ward of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Mrs. Ward suffered scar plate formation and contraction as a result of the physical properties of the TVT device. These conditions are documented in my independent medical evaluation (IME) of Mrs. Ward.

A. Scar Plate

During my physical examination of Mrs. Ward, I identified vaginal scarring and moderate induration along her anterior vaginal wall in the area of vaginal sulci, more so on the right side than the left side.

I have observed scar plate formation in patients such as Mrs. Ward who have had TVT slings implanted.

B. Contraction/Shrinkage

During my physical examination of Mrs. Ward, the sling material which was palpable within the scar plate noted above felt taut and sharp, more so along the right-sided of the anterior vaginal wall than on the left side.

I have observed "taut" pieces of transvaginal mesh in my clinical practice that are the result of post-implantation contraction and/or shrinkage of the mesh. The post-implantation shrinkage of the mesh involves a combination of two factors: one

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being the mesh itself contracting and the other being the mesh-induced foreign body response generating a fibrotic response that entails wound contracture.

Case Specific Opinion No. 2

Mrs. Ward's pelvic pain and dyspareunia were caused by scar plate formation around the TVT device as well as mesh contraction. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury (7) lichen sclerosis; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

I am able to rule out erosion as a cause of Mrs. Ward's dyspareunia in 2009. There is no evidence of this in the medical records I've reviewed nor in my pelvic examination performed during my IME.

I am able to rule in scarring with reduced elasticity and contraction as causes of Mrs. Ward's vaginal pain and dyspareunia. I identified this finding during my physical examination of Mrs. Ward. Specifically, induration noted along the vaginal sulci underneath the sling as well as pain produced on palpation in this area enables me to rule in contraction and scarring as potential causes of Mrs. Ward's dyspareunia.

I am able to exclude paraurethral banding as a cause of Mrs. Ward's dyspareunia and vaginal pain because I have seen no paraurethral banding documented nor identified such during my IME.

I am able to exclude vestibulitis, and lichen sclerosis as causes of Mrs. Ward's vaginal pain and dyspareunia.

Vaginal tissue atrophy is excludable as the cause of Mrs. Ward's dyspareunia as she never was diagnosed with this condition and never had documented evidence of vaginal tissue atrophy in the reviewed medical records or during my physical examination of Mrs. Ward

I am also able to exclude pelvic floor dysfunction as the cause of Mrs. Ward's dyspareunia. The absence of documented tenderness to the pelvic floor musculature during multiple examinations enables me to reasonably exclude pelvic floor dysfunction as a potential cause of Mrs. Ward's dyspareunia.

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Case Specific Opinion No. 3

Mrs. Ward continues to have dyspareunia and pelvic pain presently. As part of my expert review and preparation of my opinion regarding Mrs. Ward, I performed an independent medical exam of this patient on June 17th, 2016. At that time, the patient reported several bothersome symptoms including voiding dysfunction, pelvic pain and dyspareunia. Her voiding dysfunction consisted of mixed urinary incontinence, primarily urgency-related. She also complained of intermittent, dull, bilateral groin pain, sometimes more intense after walking. She described having been fairly sexually active prior to her sling surgery (as she and her husband were trying to have a third child) but now not being able to have intercourse at all because of the pain. She further characterized this pain as being located just within the vaginal canal and sometimes in the groin area. Since 2010, she only attempted sex about 3-4 times. She described feeling like her husband was placing a "rough stick inside of her", noting more pain on the right than on the left. Her LAVH-BSO operation in 2015 had no impact on her pelvic pain although it did resolve her issues with vaginal bleeding. She denied any attempts at vaginal intercourse following the LAVH-BSO.

On physical exam, there was notable tenderness upon palpation along the vaginal sulci, right greater than left where there was induration consistent with scar and fibrosed vaginal tissue. As part of the foreign body reaction to synthetic mesh the periurethral, perivesical, and vaginal tissues create dense fibrotic scar tissue which compromises the elasticity and compliance of these tissues. As such, when patients present with voiding dysfunction following synthetic mesh sling implantation, it tends to manifest itself as both obstructive in nature in combination with mixed urinary incontinence (MUI). This relates to a combination of factors, one being the development of non-compliant "pipe stem" urethral tissues that are unable to coapt and therefore hold urine; the second factor relates to a combination of (1) inflammation rendering the bladder muscle (or detrusor muscle) unstable, as well as (2) scarring of the bladder muscle adjacent to the synthetic mesh foreign body response, in which the bladder muscle's ability to contract is compromised because of scarring and fibrosis. Mrs. Ward currently has this complaint having evolved from a patient with an SUI- dominant incontinence picture to a predominantly urgency urinary incontinence (UUI) form of MUI.

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Case Specific Opinion No. 4

Mrs. Ward's future prognosis as it relates to her vaginal pain, dyspareunia, and voiding dysfunction is guarded. Because she has pelvic mesh still inside of her body, she will continue to suffer from vaginal pain and dyspareunia. Moreover, she has pelvic tenderness and residual scar tissue in the area where her mesh is located. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is challenging, complicated, and likely to create further vaginal scarring. I anticipate that if heroic surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure. Although these interventions could be somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from.

With regards to her dyspareunia, her symptoms might be partially ameliorated with sling removal. Once again, this would be a heroic procedure likely performed in a tertiary academic center and would likely create further fibrosis and scarring which would more likely than not result in persistent dyspareunia. In summary, within a reasonable degree of medical certainty, the voiding dysfunction, vaginal pain, and dyspareunia Mrs. Ward suffers from will be a lifelong condition.

I reserve the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 8th day of July, 2016

Sincerely,

Konstantin Walmsley, M.D.